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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
BRUNOVSKIS, P	
ART UNIT	**PAPER NUMBER**
1632	14

DATE MAILED: 12/05/00

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)

Office Action Summary

Application No.	Applicant(s)
09/090,672	Ishiwata et al.
Examiner	**Group Art Unit**
Peter Brunovskis	1632

☒ Responsive to communication(s) filed on *Aug 28, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1, 2, 4-7, 18, and 19* is/are pending in the applicat

Of the above, claim(s) *6* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, 4, 5, 7, 18, and 19* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The response filed 8/28/00 has been entered as well as newly amended claims 1, 2, 4-7, 18, and 19. Cancellation of claims 3, 8-17, 20, and 21 is acknowledged. Claims 1, 2, 4, 5, 7, 18, and 19 are pending in the instant application.

The status of claim 6 is unclear; claim 6 is drawn to a non-elected invention as set forth in Paper No. 9 filed 3/06/00, however, the response filed 8/28/00 (Paper No. 13) states: "By the above cancellation of claims 6, 8, 9, 14-17, 20 and 21 the provisional Election is hereby affirmed" (sentence abridging p. 4-5). However, elsewhere the response instructs to "Please cancel Claims 3, 8-17, 20 and 21" (top of p. 2) and additionally states that "Claims 1, 2, 4-7, 18 and 19 remain presented for continued prosecution" (middle of p. 8). Inasmuch as the claim 6 is drawn to a non-elected invention, it is withdrawn from consideration in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is an incomplete claim since the method steps do not clearly relate back to the preamble reciting "[a] method of treating" because it is unclear what "administering" is directed to.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4, 5, 7, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly amended claim 2, to which claims 4, 5, 7, 18, and 19 depend, recites an isolated DNA comprising a nucleotide sequence identical to any continuous 5 to 60 residues in a nucleotide sequence selected from a group consisting of various nucleotide sequences reciting specific residues that are not implicitly or explicitly described in the specification and therefore constitute new matter. There is no evidence that Applicants contemplated these embodiments at the time the invention was made. Further, the broader genera of embodiments embraced by "mRNA" (cl. 4) is broadly interpreted as being drawn to essentially any mRNA. However, there is no written description of methods broadly drawn to the scope commensurate with the claimed subject matter. The new amendment, therefore constitutes new matter. In addition, there is no

written description in the specification of any method of treating IgA nephropathy comprising administration of any isolated DNAs comprising nucleotide sequences identical to any stretch of 5 to 60 residues from any given sequence. The newly claimed method constitutes new matter.

Claims 1, 2, 4, 5, 7, 18, and 19 are rejected or remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly amended claims recite compositions or methods comprising use of isolated DNAs comprising parts or all of SEQ ID NOs:1-6 and 9-12 or isolated DNAs which hybridize with the above DNAs. The broad range of polynucleotides encompassed by the claimed subject matter define a genus whose structure and/or identity to the to the DNAs described in the claims is not described in the specification. Further, as stated in the prior Office Action, the flanking sequences may or may not have hybridization properties similar to the parent DNA and the specification does not describe what the structure of these sequences are. Inasmuch as the specification does not provide a written description of the structure characterizing members of this genus, nor traverse or even address this rejection in the response of 8/28/00, the rejected claims do not meet the written description requirement.

Claims 1, 2, 4, 5, 7, 18, and 19 are rejected or remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record because the specification, while being enabling for the specific SEQ ID Nos. 1-6 and 9-12, does not reasonably provide enablement for other nucleotide sequences comprising additional nucleotide flanking sequences and/or allelic variations . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed 8/28/00 have been fully considered but they are not persuasive. Applicants assert that amendment of claim 1 to specify what is intended by "stringent conditions" obviates the rejection as applied to claims 1, 2, 4, 5, 7, 18, and 19. No other basis for overcoming the rejection is presented. Mere incorporation of the hybridization conditions does not overcome the fact that the specification fails to teach *which* of the many allelic variants of the broad range of polynucleotides claimed in the instant invention would enable, for example, a diagnosis of IgA nephropathy in the absence of undue trial and error experimentation to determine which of the broadly drawn DNA embodiments retain the requisite properties necessary to be a diagnostic agent as per claim 5 or to serve as a therapeutic agent to treat IgA nephropathy as per claim 7. Indeed, the specification does not provide *any* teaching concerning treatment using the DNAs recited in claim 2 to which claim 7 depends.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Note: For purposes of prior art, the "diagnostic acceptable carrier" and Pharmaceutical acceptable carrier" limitations in claims 18 and 19 are given not patentable weight, since any isolated DNA in the prior art is inherently suspended in water or buffers that would meet the "carrier" limitations recited in the claims.

Claims 2, 18, and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Genbank Accession Number SYNPBR328V.

Genbank Accession Number SYNPBR328V discloses an isolated DNA comprising a nucleotide sequence containing 5 residue sequences identical to each of the first 5 residues recited in each of the newly amended SEQ ID NO:1-6, and 9-12 embodiments. Thus, nucleotides 1-5 of SEQ ID Nos:1-6, 10, and 12 match nucleotides 4065-4069, 3966-3970, 175-179, 1334-1338, 887-901, 1273-1277, 515-519, and 902-906, respectively, of SYNPBR328V. Nucleotides 31-35 of SEQ ID NO:9 is identical to nucleotides 2142-2146 of SYNPBR328V; nucleotides 48-52 of SEQ ID NO:11 is identical to nucleotides 2271-2275 of SYNPBR328V. In this instance, an

arbitrary prior art sequence, pBR328 was chosen to demonstrate that virtually any prior art sequence could be found to anticipate practically any 5 base nucleotide sequence imaginable. In this case, the first 5 nucleotides of each SEQ ID NO recited in claim 2 was found present in the arbitrarily chosen pBR328 sequence. Statistically speaking, any 5 nucleotide sequence is predicted to be randomly found every 4 x 4 x 4 x 4 x 4 = 1028 nucleotides. However, any given SEQ ID NO contains *approximately* n-4 different 5-mer sequences; a small proportion of these will be duplicated so that the total number will be somewhat smaller. Therefore, an arbitrary 500 nucleotide SEQ ID NO would have approximately 496 different 5-mer sequences, wherein any given 5-mer is predicted to be found every 1028 nucleotides; however *only one* match against the prior art is needed from any of the 496 different 5-mers to meet the limitations of the claim. The probability of *not* finding a match using a 500 nucleotide SEQ ID against *any* arbitrary sequence or 1 kilobase is essentially *zero*.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Brunovskis whose telephone number is (703) 305-2471. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda can be reached at (703) 305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to the Patent Analyst, Patsy Zimmerman whose telephone number is (703) 308-8338.

Peter Brunovskis, Ph.D.
Patent Examiner
Art Unit 1632

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER